JUL - 2 2002

K021984

Attachment A-2

510(k) Summary

510(k) Summary
for the
Inceptio Medical Technologies, L.C.
PunctSURE® Ultrasound Vascular Imaging System

1. SPONSOR

Inceptio Medical Technologies, L.C.
1401 N. Hwy 89, Suite 220
Farmington, Utah 84025

Contact Person: Bradley J. Stringer

Telephone: 801-447-7000
Fax: 801-447-7400

Date Prepared: May 30, 2002

2. Device Name

Proprietary Name:	PunctSURE® Ultrasound Vascular Imaging System
Common/Usual Name:	Diagnostic pulsed Doppler imaging system Pulse echo imaging system
Classification Name:	Diagnostic ultrasound system

3. PREDICATE DEVICES

Site~Rite 3 (K993624)

4. DEVICE DESCRIPTION

The Inceptio Medical Technologies, L.C. PunctSURE® Ultrasound Vascular Imaging System with associated transducer and accessories is designed and manufactured to provide hands-free ultrasound vascular imaging (simultaneous transverse and longitudinal views) for percutaneous vascular punctures (needle placement and vessel catheterization). The PunctSURE® System consists of three major subsystems: (1) the Transducer and Cable, (2) the Dual Image Monitor, and (3) the Sterile Vascular Imaging Procedure Kit. The sterile, single use, and disposable PunctSURE® Vascular Imaging Procedure Kit contains products used for the diagnostic procedure (magnetic laminate, acoustic coupling gel, sheath, snap ring, transducer cover, gauze sponges, and cotton swabs).

5. INTENDED USE

The Inceptio Medical Technologies, L.C. PunctSURE® Ultrasound Vascular Imaging System and associated PunctSURE® Vascular Imaging Procedure Kit are indicated for real-time imaging of selected blood vessels and nearby anatomic structures before and during percutaneous procedures, ultrasonic guidance for needle placement and vessel catheterization in a sterile environment, and Doppler confirmation of directional blood flow.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Inceptio Medical Technologies, L.C. claims equivalence of the PunctSURE® Ultrasound Vascular Imaging System to the Site~Rite 3 based on intended use, technological, and operational characteristics. A side-by-side comparison of the PunctSURE® System and the Site~Rite 3 is provided in the table below.

Side-by-Side Comparison of the
Inceptio PunctSURE® Ultrasound Vascular Imaging System
with the Dymax Site~Rite 3

Characteristic	Inceptio PunctSURE®	Site~Rite 3 Dymax K993624
Indications for Use: Vascular imaging for needle guidance	Yes	Yes
Contraindication	Implanted pacemaker	None specified
Fundamental Technological Characteristics		
Fundamental Technology	Pulsed echo ultrasound	Pulsed echo ultrasound
Real time	Yes	Yes
B-Mode	Yes	Yes
Digital	Yes	Yes
Software-controlled	Yes	Yes
Design and Operational Characteristics		
Hands free visualization	Yes	No
Doppler confirmation of directional blood flow	Yes	No
Probes	Image element: 7.5 MHz Doppler element: 5.0 MHz	9.0 MHz 7.5 MHz 5.9 MHz 3.5 MHz
Sterilizable probe (transducer)	No	No
Probe disinfection instructions provided	Yes	Yes

Side-by-Side Comparison of the
Inceptio PunctSURE® Ultrasound Vascular Imaging System
with the Dymax Site~Rite 3
(Continued)

Characteristic	Inceptio PunctSURE®	Site~Rite 3 Dymax K993624
Focal Depth	Imaging element: 20 mm ± 5 mm Doppler element: 35 mm ± 5 mm	Min: 0.5 cm (9.0 MHz probe) Max: 18 cm depth (3.5 MHz probe)
Sector angle	N/A	9.0 and 7.5 MHz probes: 26 degrees 3.5 MHz: 75 degrees
Views	Transverse and Longitudinal	Transverse or Longitudinal
Dual image monitor	Yes	No
Screen size	12.1" diagonal LCD	4 ½" diagonal CRT
Freeze frame	No	Yes
Video output	No	Yes
Battery powered	No	Yes
Battery time	Not applicable	2 hour run 5 hour recharge
Battery type	Not applicable	Nickel metal hydride
AC powered	Yes	Yes
Portable System	Yes	Yes
Accessories		
Sterile kit	Yes	Yes (from other source)
Kit contents	4 x 4 gauze Adhesive laminate Acoustic gel Probe cover (sheath) Magnetic cover Snap ring Prep tray CSR wrap Instructions	Needle guide Acoustic gel Probe cover

7. PERFORMANCE TESTING

The PunctSURE® Ultrasound Vascular Imaging System and associated PunctSURE® Vascular Imaging Procedure Kit were tested according to and demonstrated in compliance with requirements set forth in FDA Guidance

"Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"(1997) including the following, FDA-recognized, voluntary standards:

- Safety of Medical Electrical Equipment Part 2: "Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment"
- EN60601-1 Medical Electrical Equipment - Part 1, General Requirements for Safety (1988), Amendment 1 (1991), Amendment 2 (1995)
- UL2601-1, Second Edition
- CAN/CSA-C22.2 No. 601-1-M90
- IEC 60601-1-1 Medical Electrical Equipment – Part 1-1: General Requirements for Safety, Collateral Standard: Safety requirements for medical electrical systems (2000)
- IEC 60601-1-4 Medical Electrical Equipment – Part 1-1: General Requirements for Safety, Collateral Standard: Programmable electrical medical systems (2000)
- IEC 60601-2-37 Medical Electrical Equipment – Part 2-37: Particular Requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (2001)
- Electromagnetic Immunity (IEC 60601-1-2, §36.202) Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- Electromagnetic Emissions [IEC 60601-1-2: 2001, §36.201/CISPR 11: 1997, Class A; IEC 61000-3-2: Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current <= 16A per phase)(1995); IEC 61000-3-3: Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection (1995)].

In addition, verification and validation testing demonstrates that the System fulfills performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Inceptio Medical Technologies, L.C.
% Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K021984
Trade Name: PunctSURE[R] Ultrasound Vascular Imaging System,
PunctSURE[R] Vascular Imaging Procedure Kit
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Number: 21 CFR 892.1560
Regulatory Name: Ultrasonic pulsed echo imaging system
Regulatory Number: 21 CFR 892.1570
Regulatory Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: June 17, 2002
Received: June 18, 2002

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the PunctSURE[R] Ultrasound Vascular Imaging System, PunctSURE[R] Vascular Imaging Procedure Kit, as described in your premarket notification:

Transducer Model Number

Ultrasonic Piezoelectric Transducer (Part #: IN00001)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K021984

Device Name: Inceptio Medical Technologies, L.C. PunctSURE® Ultrasound Vascular Imaging System and Vascular Imaging Procedure Kit

Intended Use: Diagnostic ultrasound imaging and blood flow directional analysis as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small organ (Specify)										
Neonatal cephalic										
Cardiac										
Transesophageal										
Transrectal										
Intravascular										
Peripheral vascular		N		N		N				
Laparoscopic										
Musculoskeletal Conventional										
Musculoskeletal Superficial										
Other (Specify)										

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Indications for Use: The Inceptio Medical Technologies, L.C. PunctSURE® Ultrasound Vascular Imaging System and associated PunctSURE® Vascular Imaging Procedure Kit are indicated for real-time imaging of selected blood vessels and nearby anatomic structures before and during percutaneous procedures, ultrasonic guidance for needle placement and vessel catheterization in a sterile environment, and Doppler confirmation of directional blood flow.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021984

Prescription Use 1 (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K021984

Device Name: Inceptio Medical Technologies, L.C. PunctSURE® Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging and blood flow directional analysis as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small organ (Specify)										
Neonatal cephalic										
Cardiac										
Transesophageal										
Transrectal										
Intravascular										
Peripheral vascular		N		N		N				
Laparoscopic										
Musculoskeletal Conventional										
Musculoskeletal Superficial										
Other (Specify)										

N=New Indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

Indications for Use: The Inceptio Medical Technologies, L.C. PunctSURE® Ultrasound Vascular Imaging System and associated PunctSURE® Vascular Imaging Procedure Kit are indicated for real-time imaging of selected blood vessels and nearby anatomic structures before and during percutaneous procedures, ultrasonic guidance for needle placement and vessel catheterization in a sterile environment, and Doppler confirmation of directional blood flow.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021984

Prescription Use ✓ (Per 21 CFR 801.109)